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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/762,762	09/18/91	THOMPSON G	CGNE-69-4

EXAMINER
MOSBY, P

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ART UNIT	PAPER NUMBER
1804	16

DATE MAILED: 01/17/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9 Nov 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-67 are pending in the application.
   Of the above, claims 1-17, 19-20, 23-25, 27-32, 34, 38-40, AND 42-67 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 18, 21-22, 26, 33, 35-37, AND 41 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The specification and claims should be reviewed for spelling, grammatic, and typographic error (e.g., spelling of saturated in claim 33).

Claims 1-17, 27-32, and 42-67 stand withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made without traverse in Paper No. 15.

Applicant's election with traverse of species (c) and subspecies (c2) in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the nonelected species and subspecies are not patentably distinct. This is not found persuasive because processes involving the various species and subspecies require different starting materials and process steps as well as different end products such that the subject matter ranged from protein synthesis to enzyme inhibition for various fatty acid constituents. Thus the species and subspecies of the process claims are unrelated and have different properties as claimed and are capable of separate manufacture and use and are patentably distinct as noted in the last office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-20, 23-25, 34, and 38-40 stand withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected species and subspecies, the requirement having been traversed in Paper No. 15.

Portions of the information disclosure statements filed 20 March 1992 and 2 July 1992 were not considered because of obvious duplication and also because it is improper to cite related applications and the "references cited therein".

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

It fails to properly identify the application in that the phrase "on or about" was used to describe the filing date and in that the specification was said to have been attached to the supplied missing oath filed on 18 November 1991 while the record indicates the specification was not attached thereto.

It fails to properly identify the time period for a duty to disclose new matter in that the benefit of priority under 35 USC 120 refers to applications listed at the beginning of the specification (which was not attached or properly identified as noted above) rather than prior applications listed directly on the oath itself.

Assuming that the benefit of prior filing dates sought by applicant conforms with those listed at the beginning of the specification, the following would apply:

Analyses of transformed plants disclosed at pages 110-114 of this specification and Figure 5 (jojoba desaturase) are not found

in any prior application and do not appear to benefit from any filing date other than that of the present application which was filed on 16 September 1991.

Subject matter found in Figures 3, 4A-4C, 7B-C, and portions of Figure 8 are found in only one parent application and thus appear to benefit only from the filing date of S.N. 07/615784 (filed 14 November 1990).

All other subject matter appears to benefit at least from the earliest filing date of S.N. 07/494106 (filed 16 March 1990).

The specification is objected to because Figures 4A, 4B, 4C, 7A, 7B, and 7C presently require separate brief descriptions as set forth in 37 CFR §1.74. Correction is required.

Claims 18, 21-22, 26, 33, 35-37, and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Parentheses in claims 18 and 33 are not understood and render the claims indefinite as it is unclear whether this is optional material or not.

Claims 18 and 33 are indefinite and incomplete for failing to point out the subject matter which applicant regards as the invention in that modification of the triglyceride acyl fatty acid composition of oil is by inhibition of endogenous plant desaturase. Claims 18, 21-22, and 26 duplicate claims 33, 36-37, and 41; and claims 22 and 37 fail to further limit the invention.

Claims 21 and 36 are confusing because the processes of claims 18 and 33, which say nothing about seeds, acheive the stated result only when the elements function in the cell yet claims 21 and 36 say the elements function in seeds.

Claims 18, 21-22, 26, 33, 35-37, and 41 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what a "modifying portion of" a desaturase (claims 18 and 33) would be and this disclosure as filed sheds no light on the issue.

The content of the constructs used in the disclosed process at pages 110-114 is unclear because the written description is difficult to follow and there are no drawings of the constructs. For example, pCGN3242 (discussed at pages 106-107) either has two copies of antisense desaturase (of undetermined length and composition) under the control of two different promoters--or one copy controlled by an inserted napin promoter and it is unclear what happened to the "ACP" promoter. The pCGN3234 construct is less confusing only in the sense that at least one antisense oriented desaturase cDNA (undetermine origin and length) is under the control of a CaMV35S promoter (page 110); however, the

disclosure teaches that this does not work well and is clearly not the preferred best mode. For these reasons, the Examiner cannot determine what is necessary to acheive the stated end result. The claims are incomplete for failing to recite elements necessary to acheive the stated end result such as some type of antisense orientation for desaturase cDNA; but it is not clear what portion(s) must be in the antisense orientation or what other elements must be included in the claimed process in order to acheive the stated result based on the disclosure as filed.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph as failing to provide a full written description and enablement for practicing the claimed invention.

The process of modifying oil composition of Brassica by transformation with antisense oriented stearoyl-ACP (a.k.a. Δ9) desaturase cDNA from Brassica under the control of seed-specific promoters (pages 110-113) does not apparently produce all sorts of modifications but rather only appears to increase stearic acid in some but not all progeny and apparently in a continuously variable range of from 22.9% up to 45% in the two Brassica

species tested. The composition of the construct used, pCGN3242, (see pages 106-107) is unclear as noted above; and it is unclear whether other plasmids could be constructed which would function similarly and thus obviate a need for a deposit. The process clearly requires choice of the proper construct for success (e.g., choice of promoter) but those features which are peculiar to this plasmid or which are general features that could be constructed in any plasmid are unclear. Since it is not clear what the content of this plasmid is, the Examiner takes the position that this plasmid is essential to the invention in the absence of clear and convincing evidence to the contrary.

Since pCGN3242 (used in the example at pages 110-113) is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plasmid in a recognized utility patent depository. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if it is readily available to the public. Therefore, a deposit of plasmid is required. See 37 CFR 1.802.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See CFR 1.808.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801 - 37 CFR 1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
(e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claims 18, 21-22, 26, 33, 35-37, and 41 are rejected under under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 18, 21-22, 26, 33, 35-37, and 41 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a process of modifying oil composition of Brassica by transformation with antisense oriented stearoyl-ACP (a.k.a. Δ9) desaturase cDNA from Brassica under the control of seed-specific promoters as described at pages 110-114. The process does not apparently produce all sorts of modifications but rather only appears to increase stearic acid in some but not all progeny and apparently in a continuously variable range of from 22.9% up to 45% in the two Brassica species tested. See M.P.E.P. §§ 706.03(n) and 706.03(z). No other alteration appears

to be reproducible, for example, it is not clear what if anything happens to the oleic acid (a.k.a. 18:1) fraction which may decrease by about half in some cases (page 110) and remain unchanged in others (top of page 112, it is both decreased and increased). Limitation to specific examples actually disclosed is warranted where unique and unpredictable biochemical and genetic actions are involved. The scope of the claimed invention is not commensurate with the disclosure as filed. See In re Marzocchi, 169 USPQ 367; In re Angstadt and Griffin, 190 USPQ 214; Ex parte Hitzeman, 9 USPQ2d 1821.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 18, 21-22, 26, 33, 35-37, and 41 are rejected under 35 U.S.C. § 103 as being unpatentable over Kridl et al (6) taken with Knauf (12) and Shewmaker et al ('065) and further in view of McKeon et al (16) and Weissman et al (3).

The primary reference disclosed all features of the claimed invention including seed specific expression during lipid accumulation by means of napin promoters but differed from the disclosed invention in that the expressed gene was a sense construct of acyl carrier protein rather than an antisense construct of stearoyl-ACP desaturase as in the present invention.

The secondary references disclosed that antisense constructs of fatty acid synthesis pathway genes were a desirable means of altering plant oil composition (Knauf). Shewmaker et al taught that a cDNA sequence was all one of ordinary skill in the art needed in order to make antisense constructs for any plant gene (Shewmaker et al). The tertiary references disclosed purified protein preparations of stearoyl-ACP desaturase from safflower and its role in fatty acid synthesis (McKeon et al) and taught that purified protein preparations were all that one of ordinary skill in the art needed in order to obtain cDNA for any gene (Weissman et al).

At the time this invention was made, it was obvious to one of ordinary skill in the art to modify the primary reference with the teachings of the secondary and tertiary references in order

to obtain antisense constructs for any fatty acid pathway enzyme, including stearoyl-ACP desaturase, and down regulate expression of same in plants as suggested by Knauf with a reasonable expectation of success. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

No claim was allowed.

Any inquiry concerning this communication should be directed to P. Moody (nee Rhodes) at telephone number (703) 308-0196.

P. Moody PRM
December 15, 1992

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ART UNIT 184